

## REMARKS

Claims 8, 11-12, and 32-34 were pending. By this response, claims 8 and 11 have been amended. Accordingly, claims 8, 11-12, and 32-34 remain pending.

The following remarks are in response to the grounds for rejection of claims set forth in the Office Action.

### Rejections under 35 U.S.C. §103(a)

Claims 8, 11-12, and 32-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Edwards et al. (U.S. Patent No. 6,258,087). In response, and without acceding to any of the grounds for rejecting the claims, claim 8 has been amended to further distinguish the Edwards patent.

In particular, claim 8 has been amended to recite that the apparatus includes a "means for leaving an identifiable mark on an outer surface of a portion of tissue of the gastrointestinal lumen." and that the plurality of suction ports are located sufficiently proximate to said means for leaving an identifiable mark "such that application of suction from said suction source to said plurality of suction ports will cause the portion of tissue of the gastrointestinal lumen to contact said means for leaving an identifiable mark." These features are supported in the specification at several locations including, for example, at paragraphs 0030-32 and at FIGS. 1 and 2A-C. The function of "leaving an identifiable mark on an outer surface of a portion of tissue" is significant because the markings form the map for gastrointestinal surgery. (See paragraphs 0035-36). Accordingly, these claim limitations reflect a significant difference between the device described and claimed in the present application and the device described in the Edwards et al. patent, as described more fully below.

As noted previously, Edwards' device is an expandable electrode assembly used to treat tissue at or near a sphincter (such as the gastroesophageal junction) in the gastrointestinal tract. (See Edwards, col. 1, ll. 19-24). As the Examiner notes in the Office Action, the Edwards device includes an operative element 36 which is used "to apply energy in a selective fashion to a targeted sphincter or other body region." (Col. 10, ll. 18-20). However, in the embodiments of the Edwards device relied upon in the Office Action, the operative element is specifically configured to create subsurface lesions, and to avoid marking the surface of tissue:

The applied energy creates one or more lesions, or a prescribed pattern of lesions, below the mucosal surface of the esophagus 10 or cardia 20. The subsurface lesions are formed in a manner that preserves and protects the mucosal surface against thermal damage.

(Edwards, col. 10, ll. 21-25). See also Edwards, at column 12, ll. 22-31:

When the distal end of the electrode 66 penetrating the smooth muscle of the esophageal sphincter 18 or cardia 20 transmits radio frequency energy, the material 70 insulates the mucosal surface of the esophagus 10 or cardia 20 from direct exposure to the radio frequency energy. Thermal damage to the mucosal surface is thereby avoided. As will be described later, the mucosal surface can also be actively cooled during application of radio frequency energy, to further protect the mucosal surface from thermal damage.

Accordingly, the Edwards patent not only fails to teach or disclose a device having an electrode for marking the outer surface of tissue, the patent explicitly teaches away from such a device.

In an alternative embodiment that was not relied upon in the Office Action, the Edwards device includes an array of surface electrodes 142 carried on an expandable balloon structure 140. (See Edwards, col. 22, ll. 23-58, FIGS. 39-40). After inflating the balloon, the surface electrodes are used to ablate abnormal epithelium tissue in the esophagus. However, this alternative embodiment does not teach or disclose the "plurality of suction ports" or the proximate relation between the suction ports and the means for leaving an identifiable mark recited in the amended claims. Accordingly, this alternative embodiment also fails to teach or disclose the device recited in Applicants' claims.

Because the Edwards et al. patent fails to teach at least one element recited in claim 8, there can be no anticipation of the claim. Applicant respectfully requests withdrawal of the rejection of the claim.

All of the other claims rejected over the Edwards et al. patent depend directly from claim 8. These claims are, therefore, also patentable for the reasons set forth above.

Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should

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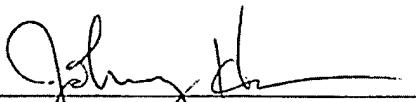
be construed as an assent to any of the Examiner's stated grounds for rejecting the claims, including specifically the Examiner's characterization of the teachings of the cited art and the Examiner's contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. USGINZ00600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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